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10/687,568	10/15/2003	Lasse Wesseltoft Mogensen	8465/40	7139

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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/687,568
Filing Date: October 15, 2003
Appellant(s): MOGENSEN ET AL.

Heidi Dare
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5 August 2009 appealing from the Office action mailed 22 April 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

10/813, 214: an appeal brief was filed 8/6/09

11/031,635: an appeal docketing notice was mailed 7/30/09

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 55, 57, 58, 66, 70, 71, and 73.

Claims 40-43, 50-54, 56, 61-65, 67 and 68 are allowed.

Claims 59, 60, 69, and 72 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner:

The rejections of claims 56 and 61-64 are withdrawn. These claims are allowed.

The rejections of claims 59, 60, 69 and 72 are withdrawn. These claims are objected to as being dependent upon a rejected base claim.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,527,287	MISKINYAR	6-1996
5,807,316	TEEPLE	9-1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 55, 57, 66, 70, 71, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Miskinyar (US 4,894,054).

Miskinyar teaches an injector device with an infusion set having a housing (74) and a hollow cannula (22), a molded device housing (10), a cover (38 and 72), a plunger (18), a drive (70), a lock (56), and the device housing being manually deformable (button 33) to release the plunger. See Figs 1 and 2.

2. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar as applied to claims above, and further in view of Teeple, Jr (US 5,807,316). Miskinyar does not teach indicia relating to the shelf life of the device on the cover. As to claim 59, see Figs 40a-40d. Teeple teaches that it is known in the art to encode the shelf life of a device in a bar code on the device (Col 18 line 25).
It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the indicia of Teeple to avoid providing an expired device to the patient. The placement of the indicia on the cover is a matter of obvious design choice since placement of the indicia anywhere on the device would have the same effect of notifying the user of expired materials.

(10) Response to Argument

1. Miskinyar

(a.i) Claims 55 and 57

The plain meaning of the term "infusion set" does not limit an infusion set to a device removable from an "injector device" (this term has not been given a special definition). An infusion set may also be a pump, an IV bag, essentially anything with a fluid conduit for subcutaneous fluid delivery. Appellant argues that by stating in the specification that an infusion set "generally includes..." they have limited the meaning of the term. Appellant's example that an infusion set must include tubing for receiving medication is not a limiting example. It is the examiner's position that "infusion set" has not been limited by the specification and one of ordinary skill in the art would consider a cannula and ampoule an

infusion set. The infusion set of Miskinyar includes an ampoule (housing) and needle (cannula) thus meeting the claimed features of a generic infusion set.

Appellants argue Miskinyar does not teach a manually deformable housing. The button 33 is a part of the housing, generally housing 10. Applicant has absolutely no basis for asserting that the button, which actually forms a top of the housing, should not be considered a housing. Applicant asserts this does not fit the plain meaning of housing, but does NOT describe what such a plain meaning would be. The button moves up and down, which makes it manually deformable from a first (up) to a second (down) position, *relative to the rest of the housing*. Thus, the *housing (as a whole)* changes shape or deforms. The button may be pushed at the sides to deploy the plunger.

(a.iii.) Claim 73

The sides of the button or top of the button, in fact any surface of the button, is a manual engagement area. The button may also be pushed at both sides to deploy the plunger.

(bi) Claim 66

See above for discussion of infusion set.

Appellant argues that the insertion set is not separable from the plunger as required by claim 66. The term "removabaly" is a capability term and the needle is capable of being removed by cutting, snapping, breaking, etc. In a device claim, the device must only be capable of, not intended or disclosed as, performing the claimed function. Furthermore, there is nothing the claims about

the needle or cannula remaining in the patient or even being removable once inside the patient, which language has been suggested by the examiner in prior interviews in this family of applications.

(bii) Claims 70 and 71

See above for discussion of the manually deformable housing.

B. Miskinyar in view of Teeple as applied to claim 58

See above for discussion of the manually deformable housing.

Applicant argues that the combination of Teeple and Miskinyar would not result in assuring sterile condition of the infusion set. This limitation is taught by Miskinyar alone. The shelf-life in the claims is not limited to the sterile shelf-life of the device. Since the device of Miskinyar includes a drug (in the ampoule) it would be obvious to list the shelf life of that drug on the cover of the device so that an expired or degraded drug is not delivered to the patient.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/ELIZABETH R MOULTON/

Examiner, Art Unit 3767

Conferees:

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767

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TC 3700 TQAS